APR 3 0 2001

510(k) Summary

SUBMITTER:
Hospal Industrie
Subsidiary of GAMBRO
B.P.126-7 Avenue Lionel-Terray
F-69883 MEYZIEU Cedex
FRANCE

APPLICANT:
COBE Cardiovascular, Inc.
Division of Sorin Biomedica
14401 W. 65th Way
Arvada, Colorado 80004-3599 USA

CONTACT PERSON:
Barbara Watson
Regulatory Affairs Specialist
COBE Cardiovascular, Inc.
Arvada, Colorado USA
Phone: (303) 467-6018
Fax: (303) 467-6429

DATE PREPARED: August 1, 2000

DEVICE TRADE NAME: COBE® HC 700 Midi Hemoconcentrator

COMMON/USUAL NAME: Hemoconcentrator

CLASSIFICATION NAME: Dialyzer, High Permeability With or Without Sealed Dialysate System

PREDICATE DEVICE: COBE® HC 1400 Maxi Hemoconcentrator

DEVICE DESCRIPTION:

The COBE® HC 700 Midi Hemoconcentrator is a sterile, non-pyrogenic device, for single use only, and is not to be resterilized by the user. The COBE® HC 700 Hemoconcentrator is intended to be used to concentrate blood that has been diluted during cardiopulmonary bypass surgery. The COBE® HC 700 Hemoconcentrator removes plasma water and dissolved solutes from blood, thereby concentrating the red cell mass and plasma proteins.

The device will be sold either individually or as part of a heart/lung pack.

The COBE® HC 700 Hemoconcentrator consists of a transparent housing with two ¼" luer locking filtrate ports. A transparent blood header cap with a 3/16" luer locking blood port is bonded to each end of the housing. Inside the housing are multiple hollow fibers. These fibers are bonded within the housing with urethane.

INDICATIONS FOR USE

The COBE® HC 700 Midi Hemoconcentrator is intended to be used during and after cardiopulmonary bypass surgery to concentrate blood that has been diluted during cardiopulmonary bypass surgery. The COBE® HC 700 Hemoconcentrator removes plasma water and dissolved solutes from blood, thereby reconcentrating the red cell mass and plasma proteins.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® HC 700 Midi Hemoconcentrator is substantially equivalent to the COBE® HC 1400 Maxi Hemoconcentrator. Both devices are equivalent in intended use, design features, and method of operation. Both devices have a transparent housing with filtrate ports, blood header caps with inlet and outlet ports, and multiple hollow fibers bonded within the housing for the removal of excess fluid via filtration.

The following tests were performed to demonstrate substantial equivalence of the COBE® HC 700 Midi Hemoconcentrator to the COBE® HC 1400 Maxi Hemoconcentrator:

1. priming volume
2. blood side pressure drop
3. ultrafiltration rate
4. sieving coefficient
5. hemoconcentrator integrity
6. blood trauma, including measurement of plasma free hemoglobin, white cell depletion, platelet depletion, and index of hemolysis
7. first pass hemolysis
8. first ultrafiltrate plasma free hemoglobin
9. single pass plasma free hemoglobin production

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2001

Ms. Barbara Watson
Regulatory Affairs Specialist
COBE® Cardiovascular, Inc.
14401 W. 65th Way
ARVADA CO 80004-3599

Re: K003023
COBE® HC 700 Midi Hemoconcentrator
Dated: January 23, 2001
Received: January 31, 2001
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Ms. Watson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K003023/01
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Indications For Use

510(k) Number (If known): K003023

Device Name:

COBE® HC 700 Midi Hemoconcentrator

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003023

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